

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

911

Bartle, J.

July 10, 2013

Tamara J. Schatz ("Ms. Schatz" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Michael F. Schatz, Ms. Schatz's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2005, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam U. Ansari, M.D., F.A.C.C. Based on an echocardiogram dated November 6, 2004, Dr. Ansari attested in Part II of Ms. Schatz's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴ Based on such findings

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Ansari also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$590,261.⁵

In the report of claimant's echocardiogram, Dr. Ansari stated that claimant had "[l]eft atrium enlargement (43 mm in anterior-posterior [sic] axis and 56-64 mm in superior-inferior [sic] axis)." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id.

§ IV.B.2.c.(2)(b)ii).

In May, 2007, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. Specifically, Dr. Yao stated claimant's "[l]eft atrial dimension is not increased" and measured her left atrial dimension to be 37 mm in the parasternal long axis view and 50 mm in the apical four chamber view.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had moderate mitral regurgitation, we need not resolve this issue given our disposition regarding claimant's left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim.

Based on the auditing cardiologist's finding that claimant did not have an abnormal left atrial dimension, the Trust issued a post-audit determination denying Ms. Schatz's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a supplemental opinion from Dr. Ansari, who confirmed his finding of an abnormal left atrial dimension based on "qualifying [left atrial enlargement] (41 mm in anterior-posterior [sic] axis and 59-63 mm in superior-inferior [sic] axis)." Dr. Ansari explained that, unlike the auditing cardiologist, he measured claimant's left atrial dimension and also provided several still-frame images that purportedly demonstrated an abnormal left atrial dimension. Claimant also argued that: (1) her additional echocardiograms demonstrated a worsening condition; (2) the auditing cardiologist's report contained many inconsistencies; (3) the Trust was not "neutral, fair, and timely" in assessing her claim; and (4) the Trust failed to specify the auditing cardiologist's credentials in connection with its denial.⁷

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schatz's claim.

7. The Trust provided claimant with Dr. Yao's credentials with its final post-audit determination.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Yao submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Schatz suffered from an abnormal left atrial dimension. Specifically, Dr. Yao stated:

With respect to left atrial dimension as seen on the November 6, 2004 study, I affirm my findings at audit that Claimant's left atrial dimensions measure 37mm in the parasternal long-axis view and 50mm in the apical four-chamber view.

The Trust then issued a final post-audit determination, again denying Ms. Schatz's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Schatz's claim should be paid. On February 6, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7666 (Feb. 6, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 11, 2008, and claimant submitted a sur-reply on December 16, 2008. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Schatz mainly reasserts the arguments she made in contest. In addition, claimant argues that there is a reasonable medical basis for finding an abnormal left atrial dimension because she has an increased left atrial volume. She also contends that the Trust lacks "verifiable evidence" to support the auditing cardiologist's determination that her echocardiogram did not demonstrate an abnormal left atrial dimension. Finally, claimant asserted that the Trust's audit process is flawed and unfair to claimants.⁹

In response, the Trust asserts that the findings of the auditing cardiologist demonstrate there is no reasonable medical basis for Dr. Ansari's finding of an abnormal left atrial dimension. The Trust also contends that Dr. Yao's credentials establish his independence and that claimant's argument challenging his impartiality do nothing to establish a reasonable medical basis for her claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Specifically, Dr. Vigilante determined that:

9. Claimant also asserted that the auditing cardiologist has an appearance of a conflict of interest because he was a speaker for several pharmaceutical companies, although not any drug manufacturer associated with these proceedings. As there is no evidence that the auditing cardiologist had a conflict of interest, this issue is irrelevant for resolution of this claim.

Visually, the left atrium appeared at the upper limits of normal in size. I digitized the cardiac cycles in the parasternal long-axis and apical four chamber views in which the left atrium appeared at the largest. I measured the left atrium by electronic calipers. I determined that the left atrial antero-posterior diameter was 3.8 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. The sonographer's largest left atrial diameter in the parasternal long-axis view was 4.27 cm. This measurement was taken on a diagonal. Dr. Ansari's antero-posterior diameter determination was 4.07 cm noted on the still frame. As can be seen on this image, the distal point of the measurement went past the back wall of the left atrium and was inaccurate. I determined that the left atrium measured 5.2 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement. Dr. Ansari measured left atrial diameters of 5.91 cm and 6.24 cm in the supero-inferior axis. As can be noted on the still frames, the first measurement was at the mitral valve leaflet tips rather than the mitral annulus and was past the back wall of the left atrium. The second measurement was into the pulmonary vein. My [left atrial area] determination of 19.6 cm² is also consistent with a left atrial size at the upper limits of normal and corresponds to the above left atrium measurements. In summary, the left atrial diameter is within normal limits as per the Settlement Agreement.

....

[T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question F.5. That is, when appropriate measurements are taken, the echocardiogram of November 6, 2004 demonstrated normal left atrial dimensions with comments above. An

echocardiographer could not reasonably conclude that abnormal left atrial dimension was present on this study even taking into account inter-reader variability.

In response to the Technical Advisor report, claimant argues that the Technical Advisor's finding regarding her left atrial dimension is not based on reliable principals and methods because the Technical Advisor does not depict any measurements, i.e., he did not provide any still-frame images that demonstrate the points of measurement and the results. In addition, Ms. Schatz contends that it is not possible for an echocardiogram to demonstrate moderate mitral regurgitation but not show an enlarged left atrium greater than 5.3 cm. Ms. Schatz also asserts that Dr. Ansari correctly measured her left atrial dimension. Finally, claimant notes that the Technical Advisor failed to reference the volume of her left atrium.

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant that Dr. Ansari's supplemental opinion and still-frame images provide a reasonable medical basis for his representation that Ms. Schatz has an abnormal left atrial dimension. Dr. Yao reviewed claimant's November 6, 2004 echocardiogram and determined that it demonstrated a left atrial supero-inferior systolic dimension of 3.7 cm and a left atrial antero-posterior diastolic dimension of 5.0 cm.¹⁰ Although

10. For this reason as well, we reject claimant's argument that the Trust lacked "verifiable evidence" to support its denial of (continued...)

Dr. Ansari provided still-frame images purportedly demonstrating a left atrial supero-inferior systolic dimension of 4.1 cm and a left atrial antero-posterior diastolic dimension of between 5.9 cm and 6.3 cm, Dr. Yao reviewed these images and confirmed his findings at audit.¹¹

In addition, Dr. Vigilante reviewed claimant's November 6, 2004 echocardiogram and determined that claimant's left atrial supero-inferior systolic dimension was 3.8 cm and her left atrial antero-posterior dimension was 5.2 cm. Dr. Vigilante also reviewed the still-frame images provided by Dr. Ansari and determined they were not accurate. Specifically, Dr. Vigilante noted, with respect to Dr. Ansari's measurement of claimant's left atrial supero-inferior systolic dimension, that "the distal point of the measurement went past the back wall of the left atrium and was inaccurate." With respect to Dr. Ansari's measurements of claimant's left atrial antero-posterior diastolic dimension, Dr. Vigilante observed that "the first measurement was at the mitral valve leaflet tips rather than the mitral annulus and was past the back wall of the left atrium." Dr. Vigilante

10. (...continued)
her claim.

11. We reject Ms. Schatz's argument that she is entitled to relief because the auditing cardiologist's report contained inconsistencies. First, Dr. Yao correctly indicated that Ms. Schatz's claim was based only her November 6, 2004 echocardiogram. Second, although Dr. Yao indicated on page 3 of the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue that Ms. Schatz had trace aortic regurgitation, that option is not available on page 6, where he selected no aortic regurgitation.

concluded that "[t]he second measurement was into the pulmonary vein." Dr. Vigilante also noted that his left atrial area determination of 19.6 cm², which is used to calculate the level of mitral regurgitation, "is also consistent with a left atrial size at the upper limits of normal and corresponds to the above left atrium measurements."¹²

Moreover, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include, among other things, overtracing the amount of a claimant's regurgitation.

See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26.

Similarly, as noted above, Dr. Vigilante determined that Dr. Ansari's measurement of claimant's left atrial supero-inferior systolic dimension "went past the back wall of the left atrium and was inaccurate" and that his measurements of claimant's left atrial antero-posterior diastolic dimension were "at the mitral valve leaflet tips rather than the mitral annulus and was past the back wall of the left atrium" and were "into the pulmonary vein." Such unacceptable practices cannot provide a

12. Thus, we reject claimant's argument that it is inconsistent to find moderate mitral regurgitation and a normal left atrial dimension.

reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from an abnormal left atrial dimension.

We also reject claimant's argument that she may rely on the volume of her left atrium to establish a reasonable medical basis for Dr. Ansari's representation that claimant has an abnormal left atrial dimension. As stated, the Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii). We previously have held that neither the Trust nor a claimant may prove or disprove the existence of a particular medical condition by a method other than that which is specifically required by the Settlement Agreement. See, e.g., Mem. in Supp. of PTO No. 8562 at 12 n.11 (Nov. 15, 2010).¹³

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of

13. We similarly reject claimant's argument that claimant's additional echocardiograms provide a reasonable medical basis for Dr. Ansari's representation of an abnormal left atrial dimension because they demonstrate a worsening condition. As Dr. Ansari's representation was based on claimant's November 6, 2004 echocardiogram, the results of other echocardiograms are irrelevant.

Ms. Schatz's claim for Matrix Benefits and the related derivative
claim submitted by her spouse.